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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,296	06/11/2007	Yusuke Nakamura	082368-009400US	2495
20350 7590 01/24/2008 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER AEDER, SEAN E	
			ART UNIT 1642	PAPER NUMBER
			MAIL DATE 01/24/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/598,296

Applicant(s)

NAKAMURA ET AL.

Examiner

Sean E. Aeder

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

It is noted that the claims of the instant application have been determined to include linking claims. Claim 1 link(s) inventions I-II, as set forth below. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/ are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group I, claim(s) 2-12, as specifically drawn to methods for diagnosing a predisposition to developing PRC in a subject comprising determining the level of PRC-associated polynucleotides.

Group II, claim(s) 2-7, 10, and 11, as specifically drawn to methods for diagnosing a predisposition to developing PRC in a subject comprising determining the level of PRC-associated polypeptides.

Group III, claim(s) 13-15, as specifically drawn to a PRC expression profile comprising a pattern of gene expression.

Group IV, claim(s) 16, 28, and 32, as specifically drawn to a method of screening for a compound comprising contacting a test compound with a polypeptide encoded by a PRC, detecting binding activity between the polypeptide and the test compound, and

selecting a compound that binds the polypeptide, a method of treating with said compound, and said compound.

Group V, claim(s) 17, 18, 28, and 32, as specifically drawn to a method of screening for a compound comprising contacting a candidate compound with a cell expressing one or more marker genes, and selecting a compound that reduces that expression level or elevates that expression level of said one or more marker genes, a method of treating with said compound, and said compound.

Group VI, claim(s) 19, 28, and 32, as specifically drawn to a method of screening for a compound comprising contacting a test compound with a PRC polypeptide, detecting the biological activity of the polypeptide, and selecting a compound that suppresses or activates the biological activity of the polypeptide in the presence of the compound in comparison with the biological activity detected in the absence of the compound, a method of treating with said compound, and said compound.

Group VII, claim(s) 20, 28, and 32, as specifically drawn to a method of screening for a compound comprising contacting a candidate compound with a cell into which a vector comprising the transcriptional regulatory region of one or more marker genes and a reporter gene under the control of the transcriptional regulatory region, measuring the expression or activity of said reporter gene, and selecting a compound that reduces or enhances the expression of said reporter gene, a method of treating with said compound, and said compound.

Group VIII, claim(s) 21-22, drawn to products comprising reagents that bind to two or more PRC nucleic acids.

Group IX, claim(s) 23-24, drawn to a method of treating or preventing PRC in a subject comprising administering antisense or siRNA constructs to PRC genes.

Group X, claim(s) 25, drawn to a method of treating or preventing PRC in a subject comprising administering antibodies or fragments thereof that bind PRC proteins.

Group XI, claim(s) 26, as specifically drawn to a method of treating or preventing PRC in a subject comprising administering a PRC polypeptide encoded by PRC 1-40.

Group XII, claim(s) 26, as specifically drawn to a method of treating or preventing PRC in a subject comprising administering a PRC 1-40 polynucleotide.

Group XIII, claim(s) 27 and 29, as specifically drawn to a method of treating or preventing PRC in a subject comprising administering a compound that increases the expression or activity of PRC 41-138 and a method of treating or preventing PRC in a

subject comprising administering a polynucleotide selected from the group consisting of PRC 41-138.

Group XIV, claim(s) 29, as specifically drawn to a method of treating or preventing PRC in a subject comprising administering a polypeptide encoded by a polynucleotide selected from the group consisting of PRC 41-138.

Group XV, claim(s) 30, as specifically drawn to a composition comprising an antisense polynucleotide or a siRNA against a polynucleotide selected from the group consisting of PRC 1-40.

Group XVI, claim(s) 31, as specifically drawn to a composition comprising an antibody or fragment thereof that binds to protein encoded by any one gene selected from the group consisting of PRC 1-40.

The inventions listed as groups I-XVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-XVI appears to be that they all relate to the special technical feature of methods for diagnosing a predisposition to developing PRC in a subject comprising determining the level of PRC-associated polynucleotides.

However, Aoyagi et al (Clinical Cancer Research, September 1998, 4:2153-2160) teaches methods for diagnosing a predisposition to developing PRC in a subject comprising determining the level of PRC-associated polynucleotides (see right column of page 2160, in particular).

Therefore, the technical feature linking the inventions of groups I-XVI does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Accordingly, groups I-XVI are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Species

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Claims 1-12, 16-20, 23-29, and 32 are generic to a plurality of disclosed patentably distinct species of **methods involving one or a specific combination of PRC-associated genes**. Each one or combination of PRC-associated genes represents a

species. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The methods of the above species differ at least in objectives, method steps, reagents, and criteria for success such that one species could not be interchanged with the other. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Claims 13-15 are generic to a plurality of disclosed patentably distinct species of **expression profiles of specific combinations of PRC-associated genes**. Each combination of PRC-associated genes represents a species. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species represent separate and distinct expression profiles. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Claims 21-22, 30, 31 are generic to a plurality of disclosed patentably distinct species of **products represented by one or a specific combination of PRC-associated genes**. Each one or combination of PRC-associated genes represents a species. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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